



THE PHARMACOECONOMIC IMPACT OF ANTIMICROBIAL THERAPY FOR PEPTIC ULCER DISEASE IN A LARGE URBAN JAIL

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ABSTRACT

Purpose. To determine the pharmacoeconomic impact of antimicrobial treatment of peptic ulcer disease (PUD) in a large urban jail.

Patients and Methods. Retrospective comparison of PUD-related pharmacy and laboratory expenditures over a 2-year period before and after the institution of a PUD treatment protocol with the priority of *Helicobacter pylori* eradication for inmates in Rikers Island Correctional Facility.

Results. After the protocol was adopted, total pharmacy-related and laboratory-related expenses for PUD care decreased by 40.2%, and expenditures for ranitidine declined by 52.2%. There was an increase in spending for antimicrobial agents and *H. pylori* antibody testing, but this was insignificant compared to the savings generated by decreased ranitidine usage. Annual savings in our facility as a result of this intervention were \$123,449.

Conclusions. Modern therapeutic strategies for PUD aimed at eradicating *H. pylori* can result in significant savings in the institutional setting; these savings are largely attributable to the decreased usage of histamine-2 receptor antagonists.

KEY WORDS Cost, Jail, Peptic ulcer disease, Treatment.

INTRODUCTION

Peptic ulcer disease (PUD) is a common condition and is associated with substantial morbidity and mortality. Long-term histamine-2 (H-2) receptor antagonist therapy has been a mainstay of PUD management, with ranitidine being among

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the most widely dispensed medications in the US.¹ In recent years, the etiologic role of *Helicobacter pylori* in PUD has been firmly established. The majority of duodenal ulcers and most gastric ulcers are attributable to this pathogen.² Eradication of the organism is associated with the virtual elimination of recurrent disease, in contrast to the high rate of recurrence seen with non-eradication therapy.² A cost-benefit analysis published recently concluded that empiric antimicrobial therapy of suspected PUD is the most cost-effective approach currently available.³ In October 1995, we initiated a protocol at Rikers Island, New York City's largest jail, that assigned priority to *H. pylori* eradication, and we instituted limitations on the chronic use of H-2 blockers. We report on changes in PUD-associated expenditures as a result of this intervention.

METHODS

SETTING

Rikers Island is New York City's largest correctional facility, housing approximately 15,300 detainees for median and mean lengths of stay of approximately 28 and 61 days, respectively. Males comprise 89% of the inmate population and have a mean age of 31 years. The mean age of females is 34 years. More than 90% of the prisoners of both genders belong to ethnic minority groups, and more than 55% are African-American. On-site medical care is delivered by Montefiore Medical Center, the contractual provider for New York City. Databases are maintained by the pharmacy and clinical laboratory for all medication orders and off-premises laboratory tests. Gastroenterology subspecialty clinic appointments are available at local municipal hospitals.

INTERVENTION

Beginning October 15, 1995, a protocol established three classifications for patients with dyspepsia: "definite" PUD, having a present or past history of endoscopically or radiographically diagnosed PUD; "likely" PUD, lacking prior proven PUD but reporting "classic" symptoms, including recurrent epigastric discomfort, especially if occurring preprandially or nocturnally and relieved by eating; and "unlikely" PUD, having dyspepsia but lacking "definite" or "likely" criteria. Those PUD patients classified as definite and without prior therapy for *H. pylori* were offered eradication antimicrobial treatment, as were patients in the likely

a component of the Correctional Health Services of the New York City Department of Health and the New York City Health and Hospitals Corporation.

This work was presented in part at the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana, September 15-18, 1996.

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category with antibodies against *H. pylori*. Patients in the likely category who were seronegative were offered either ranitidine or antacids, as well as gastroenterology consultation. Patients in the unlikely category were offered observation or antacids. All patients with persistent symptoms despite therapy were referred for gastroenterology consultation. After the initiation date of the new protocol, ranitidine, the only H-2 blocker in the formulary, was subject to automatic discontinuation by the pharmacy after 14 days. The responsible physician had the unrestricted right to override the discontinuation by completing a simple form and renewing the order.

Eradicative antimicrobial therapy consisted of tetracycline 500 mg qid, metronidazole 250 mg tid, and bismuth subsalicylate 2 tablets qid, along with ranitidine 300 mg at bedtime, all given orally for 14 days, a regimen with an expected efficacy of 90%.⁴⁻⁶ Tetracycline-intolerant patients received amoxicillin 500 mg orally qid instead.

Because the clinical activities and data acquisition described here were performed as part of the routine medical care and quality assurance process on Rikers Island, neither informed consent nor institutional review board oversight was sought.

DATA SOURCES

Records of monthly pharmacy expenditures for the medications listed above were available for all of 1995 and 1996; laboratory expenditures for *H. pylori* serologies were available from June 1995 through the end of 1996. Bismuth subsalicylate tablets were added to the Rikers Island formulary in October 1995. Spending on bismuth subsalicylate prior to October 1995 and on *H. pylori* testing prior to June 1995 were assumed to be zero for the sake of the present analysis. Usage of antacids constituted less than 5% of the overall expenditure, which did not change significantly after the intervention, and was thus not included in the analysis. Monthly Rikers Island census data were obtained from the New York City Department of Corrections. We calculated point prevalences of active ranitidine orders by counting active orders in the pharmacy database on a given day of each study month, at 30-day intervals, and dividing by the concurrent Rikers Island census. These statistics, as well as the duration of ranitidine therapy for each recipient, were available in the Rikers Island pharmacy database from August 1995 through June 1996.

STATISTICAL ANALYSIS

All statistical analyses were performed with SPSS for Windows version 6.1.2. (SPSS Inc., Chicago, IL). Continuous variables were compared using the Student

t test for independent samples or by Wilcoxon rank sum test for data that were not distributed normally.

RESULTS

Monthly pharmacy expenditures for ranitidine, tetracycline, metronidazole, and bismuth subsalicylate and laboratory expenditures for *H. pylori* serologic testing are depicted in the Figure. Annualized total costs decreased by 40.2%, from \$307,331 to \$183,882 ($P = .002$). Annualized expenditures for ranitidine decreased by 52.2% ($P < .001$), while spending for antibiotics and serotesting increased by 6.2-fold ($P < .001$) and 9.7-fold ($P < .001$), respectively. The net overall cost reductions were not attributable to changes in patient census, which actually increased between 1995 and 1996.

In a separate analysis of practitioner ordering practices, active orders for ranitidine dropped sharply after the protocol start date. The mean point prevalence of active ranitidine orders decreased 35.5% after the intervention, from 9.82 to 6.33 orders per 1,000 inmates ($P = .05$). A simultaneous decline in the mean duration of ranitidine treatment from 55.3 to 24.1 days was also observed ($P < .001$).

DISCUSSION

The present study demonstrates significant cost savings as a result of the adoption of a modern PUD treatment strategy in a large correctional facility. There is now

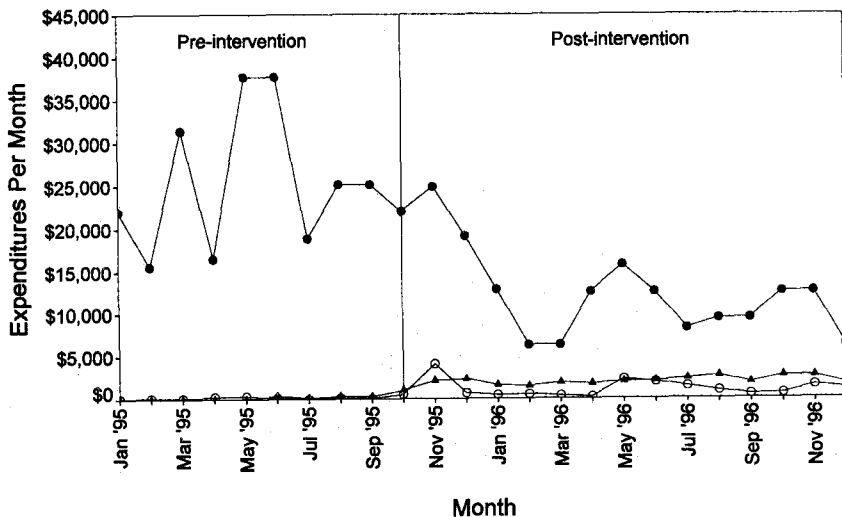


FIGURE Expenditures related to peptic ulcer disease by month. The new protocol was introduced at Rikers Island in October 1995. Lines depict spending on ranitidine (●), antimicrobial agents (○), and *Helicobacter pylori* serology testing (▲). Data were not available for serology testing prior to June 1995. Antimicrobial therapy consisted of tetracycline, metronidazole, and bismuth subsalicylate.

universal agreement that proven PUD in the setting of *H. pylori* infection is best managed through eradication antimicrobial therapy.^{7,8} The practice of treating PUD empirically has been commonplace for over a decade,⁹ and a fully empiric approach to treating suspected PUD with eradication antimicrobial therapy was shown to maximize cost-effectiveness in a recent decision analysis, which also commented that *H. pylori* antibody testing may be a worthwhile method of minimizing the excessive prescription of unnecessary antibiotics if the unit price of testing were less than the \$80 employed in their calculations.³ Given the per test charge of approximately \$15 available to our patients, we utilized the serology for patients with typical PUD symptoms who lacked a prior diagnosis of PUD. This treatment strategy, therefore, may best be termed semiempiric.

The outcome analysis conducted after the new protocol was implemented showed that the widespread, long-term usage of H-2 blockers, no longer the preferred treatment for most cases of PUD, was markedly reduced, while the use of antimicrobial agents for eradication therapy, along with *H. pylori* antibody testing, substantially increased. Patients having PUD on Rikers Island, therefore, were more likely to receive modern, "first-line" treatment than they were prior to the institution of the new policy. One would expect, from results of prior published studies, that PUD patients receiving this therapy would have an 80–90% likelihood of achieving a long-term cure, as opposed to the chronic remissions and exacerbations associated with H-2 blocker therapy.^{4,5} The cost savings reflect the low price ratio of eradication antimicrobial therapy to long-term H-2 blockers. It should be pointed out that an analysis conducted in a correctional facility with a short average length of stay would tend to underestimate the true savings generated by a 14-day program of curative therapy compared to long-term, noncurative therapy, because an analysis in such a setting is more likely to capture the full cost of the 14-day therapy and only a fraction of the long-term alternative therapy costs. It is likely that savings in a community-based sample with longer follow-up would be significantly higher.

Certain limitations of the present study require mention. Although Rikers Island samples a substantial subset of the New York City population, findings in a jail population are not necessarily generalizable to the larger community. There is no obvious reason, however, that the principles of PUD treatment or the efficacy thereof would be different for inmates. All usage of ranitidine, tetracycline, metronidazole, and bismuth subsalicylate on Rikers Island was assumed to be for the purpose of PUD care, and spending on bismuth subsalicylate and serotesting was assumed to be zero in the preintervention months, for which data were not available. These assumptions would tend to diminish the power

of the analysis to detect a decrease in expenditures, leading to an underestimation of actual savings. Finally, the study was not designed to evaluate clinical outcomes. The study hypothesis and design were structured to measure the institutionwide budgetary impact of a patient care protocol and hence individual patient information was not collected or analyzed. While we are not aware of any obvious changes in PUD-related morbidity and mortality patterns in our facility since the intervention, major events may occur too infrequently to be detected in an analysis of this size. It is unlikely that non-pharmacy-based expenditures have increased to offset our savings, since other studies have convincingly demonstrated a decrease in morbid events and PUD-related health care costs in patients who were treated with eradication antimicrobial therapy versus H-2 blockers.^{10,11} It is quite possible, therefore, that the savings observed in this study represent just the "tip of the iceberg" when other sources of long-term savings are considered.

The association of *H. pylori* with PUD represents an important advance in medical science. The optimal diagnostic techniques and treatment modalities for PUD associated with *H. pylori* remain subjects of debate and controversy. We have opted to employ a semiempiric approach, which expands the role of eradication antimicrobial therapy and minimizes the long-term usage of ranitidine. While modernizing our treatment of PUD in a large urban jail, we have generated significant, sustained cost savings within our pharmacy budget. Contrary to popular impression, advances in medical science, in certain instances, may result in improved care at reduced cost.

ADDENDUM

As of January 1, 1998, after the preparation of this manuscript, the relationship between New York City and Montefiore Medical Center to provide care to the inmates of Rikers Island Correctional Facility was dissolved. Statements in this paper that reflect principles and practice of care within the facility may no longer pertain.

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